

### **REMARKS**

This Amendment is filed in response to the Office Action mailed September 16, 2011 ("*Office Action*"). In this Amendment, claims 23 and 40 are amended, and claims 24-28 and 41 are unchanged. Claims 29-39 were previously withdrawn, and claims 1-22 were previously canceled. Following entry of this amendment, claims 23-28, 40, and 41 shall be pending.

In the *Office Action*, claims 23-28, 40, and 41 were rejected based on prior art grounds. For the reasons set forth below, these rejections are hereby traversed.

#### **I. REJECTIONS UNDER 35 U.S.C. § 103**

Claims 23-28, 40, and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,231,597 to Deem et al. ("*Deem*") in view of U.S. Patent No. 6,309,367 to Boock ("*Boock*"). Of these claims, claims 23 and 40 are independent claims. Claims 24-28 are dependent claims that depend either directly or indirectly from claim 23, and claim 41 is a dependent claim that depends from claim 40. For at least the reasons set forth below, it is submitted that these prior art rejections should be withdrawn and the pending claims allowed.

Without conceding to the merits of the rejections, independent claims 23 and 40 have been amended. Amended claim 23 recites a device for treating a vascular aneurysm comprising: a support structure sized for placement at a region of said vascular aneurysm; said support structure having a bridge portion spanning at least a neck region of said vascular aneurysm; said support structure having an open, non-tubular arced configuration; said bridge portion including a reactive material, said reactive material being volumetrically expanded when in a reacted state such that said bridge portion restricts flow of blood to said vascular aneurysm when said reactive material is in said reacted state, said bridge portion substantially free of protrusions therefrom when said reactive material is in said reactive state.

Amended claim 40 recites an implant for treating a vascular aneurysm comprising: an implant body sized to reside at a region of said vascular aneurysm; said implant body having an occlusion region that substantially traverses a neck region of said vascular aneurysm; said implant body having an arc shape, said arc shape having a sweep less than 360 degrees; said occlusion region including a reactive material, said reactive material being volumetrically expanded when in a reacted state such that said occlusion region substantially restricts flow of blood to said vascular aneurysm when said reactive material is in a reacted state, said occlusion region substantially free of protrusions therefrom when said reactive material is in said reactive state. Support for these amendments can be found throughout the present application as published in U.S. Publication No. 2004/0186562 and, more particularly, at least in paragraph [0075] and Figs. 10-12.

*Deem* in view of *Boock* cannot be properly relied upon as making obvious the present invention for at least two reasons. First, *Deem* in view of *Boock* fails to teach or make obvious the claimed “said bridge portion substantially free of protrusions therefrom when said reactive material is in said reactive state,” as recited in claims 23, and the claimed “said occlusion region substantially free of protrusions therefrom when said reactive material is in said reactive state,” as recited in claim 40.

In the *Office Action*, the Examiner concedes that *Deem* fails to teach or make obvious the claimed “said reactive material being volumetrically expanded when in a reacted state,” as recited in claims 23 and 40. Pp. 3-4, ¶ 6. The Examiner asserted that *Boock* overcomes this deficiency of *Deem* by teaching the swellable polymer bit 94. *Id.* *Boock* teaches that the bit 94 “is positioned on an inside surface, facing the aneurysm. The material, such as is shown in FIG. 14, swells, and the polymer or similar material **fills the neck of the aneurysm beyond the shield**, further sealing and supporting the shield.” Col. 4, lines 15-21 (Emphasis added). Figs. 13 and 14 of *Boock* clearly show bit 94 protruding or projecting out from the shield main body 92.

Accordingly, *Boock* actually teaches away from the claimed bridge portion substantially free of protrusions therefrom when said reactive material is in said reactive state,” as recited in claim 23, and the claimed “said occlusion region substantially free of protrusions therefrom when said reactive material is in said reactive state,” as recited in claim 40. Hence, withdrawal of the present rejections and an indication of allowance are respectfully requested.

Second, the present rejections are improper because the Examiner’s proposed modifications would improperly modify the principle of operation of the stent of *Deem*. Section 2143.01 VI of the M.P.E.P. states, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.” The purpose of the stent of *Deem* is to obstruct flow to an aneurysm while simultaneously minimizing obstruction of flow through the healthy vessel. Col. 5, lines 18-22. The principle of operation of the stent taught by *Deem* is simply to ***span the neck of the aneurysm***, by deployment of the stent at the site of interest and orientation of the mid-region 15 across the opening of the vascular abnormality—*not* to into the neck of the aneurysm. Col. 5, lines 45-54.

In contrast, as described above, the swellable polymer bit 94 of *Boock* extends outward from the main body 92 and into the neck of the aneurysm. Col. 4, lines 15-27. In other words, the swellable polymer bit 94 functions to form a ***plug that fills the neck of the aneurysm***. *Id.* Hence, including the swellable polymer bit 94 of *Boock* on the mid-region 15 of the stent taught by *Deem*, as proposed by the Examiner, would change the stent of *Deem* from a device that spans the neck of an aneurysm to a device that both spans the neck of an aneurysm *and extends into and plugs the aneurysm*.

In the *Response to Arguments* section of the *Office Action*, the Examiner asserted that:

Deem et al. provide no disclosure discouraging the addition of other materials to improve upon the device. Simply because the Deem et al. device only spans the neck of the aneurysm is not an indication that

one skilled in the art would have found the combination non-obvious. The modification would not render the Deem et al. device unsuitable for its intended purpose because it would still span the neck of an aneurysm.

P. 5, ¶ 14. The Applicants note that, based upon the above statement, it appears the Examiner has based his responses upon subsection V of section 2143.01 of the M.P.E.P.—not subsection VI as argued by the Applicants. These sections, as evidenced by their separate discussion in different subsections, outline different requirements for setting forth a *prima facie* case of obviousness. Section 2143.01 VI of the M.P.E.P. only requires that “[i]f the proposed modification or combination of the prior art would **change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious.**” (Emphasis added). In contrast to the Examiner’s above quoted assertions from the *Office Action*, section 2143.01 VI of the M.P.E.P. does not link the outlined requirement for establishing a *prima facie* case of obviousness to one skilled in the art finding the combination obvious, as is the case in subsection V. Under section 2143.01 VI, it is simply impermissible that a proposed modification change the principle of operation of the prior art device.

Furthermore, the Applicants note that the Examiner’s proposed modification is not a trivial change in the principle of operation of the stent 10 of *Deem*. For example, one having ordinary skill in the art would recognize that the Examiner’s proposed modification would require increased customization of the device in order to properly fit the device not only to the dimensions of the patient’s vessel but also to the dimensions of the neck of the patient’s aneurysm.

The proposed modified device would further require a different method of deployment of the device of *Deem*. It would not be sufficient to simply deploy the device so as to simply to **span the neck of the aneurysm**, as taught by *Deem*. Col. 7, lines 40-46. The Examiner’s proposed modification would further require deployment of the device with significantly greater precision such that the swellable polymer bit is

properly aligned with the neck of the aneurysm into which it will expand. Misalignment of the swellable polymer bit of the proposed device would, in contrast to the purpose of the stent of *Deem*, likely result in **increased obstruction** of the flow through the healthy vessel, as well as an increased likelihood of potential damage to the vascular abnormality.

In view of the above, it becomes self evident that the present rejections are improper and that *Deem* in view of *Boock* fails to teach or make obvious the present invention as claimed in independent claims 23 and 40. Hence, withdrawal of these rejections and an indication of allowance are respectfully requested.

Turning to claims 24-28 and 41, these claims depend from independent claim 23 or 40 and are allowable for at least the same reasons as claims 23 and 40. However, these claims further limit the claimed invention and thus are separately patentable over the cited prior art.

## **II. RELATED APPLICATIONS OF ASSIGNEE**

Applicant wishes to draw the Examiner's attention to the following related applications of the present application's assignee.

<b>Docket No.</b>	<b>Serial No.</b>	<b>TITLE</b>	<b>Filed</b>
020/DE	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/EPO	92121203.1	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/ES	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/FR	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/IT	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020/UK	547530	INTRAVASCULAR HYDROGEL IMPLANT	12/12/1992
020A/US	07/809,265	INTRAVASCULAR HYDROGEL IMPLANT	12/16/1991
023/C	09/758,832	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM, CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	01/11/2001

Applicant: Brian J. Cox  
Serial No.: 10/763,975  
Art Unit: 3731

PATENT  
Atty Docket: 388700-058B

<b>Docket No.</b>	<b>Serial No.</b>	<b>TITLE</b>	<b>Filed</b>
023/EP	97930198.3	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM), CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	06/19/1997
023A/US	08/668,229	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM), CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	006/21/1996
023C2	11/107,600	INSITU FORMABLE AND SELF-FORMING INTRAVASCULAR FLOW MODIFIER (IFM), CATHETER AND IFM ASSEMBLY, AND METHOD FOR DEPLOYMENT OF SAME	04/15/2005
029A	09/906,415	METHODS, MATERIALS AND APPARATUS FOR DETERRING OR PREVENTING ENDOLEAKS FOLLOWING ENDOVASCULAR GRAFT IMPLANTATION	07/16/2001
029G	10/726,135	METHODS, MATERIALS AND APPARATUS FOR DETERRING OR PREVENTING ENDOLEAKS FOLLOWING ENDOVASCULAR GRAFT IMPLANTATION	12/01/2003
029/PCT	PCT/US2002/22242	METHODS, MATERIALS AND APPARATUS FOR DETERRING OR PREVENTING ENDOLEAKS FOLLOWING ENDOVASCULAR GRAFT IMPLANTATION	07/12/2002
029/EPO	02748152.2	METHODS, MATERIALS AND APPARATUS FOR DETERRING OR PREVENTING ENDOLEAKS FOLLOWING ENDOVASCULAR GRAFT IMPLANTATION	07/12/2002
029/JP	2003-513399	METHODS, MATERIALS AND APPARATUS FOR DETERRING OR PREVENTING ENDOLEAKS FOLLOWING ENDOVASCULAR GRAFT IMPLANTATION	07-12-2002
033/EPO	4759007	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2004
033/JP	2006-509415	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2004
033/PCT	PCT/US2004/009528	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2004
033A/US	10/400,138	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	03/25/2003

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<b>Docket No.</b>	<b>Serial No.</b>	<b>TITLE</b>	<b>Filed</b>
033B	11/678,544	METHODS AND APPARATUS FOR TREATING ANEURYSMS AND OTHER VASCULAR DEFECTS	02/23/2007
057A	09/909,715	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	07/20/2001
057A/DIV	12/510,548	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	07/28/2009
057/PCT	PCT/US2002/019676	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	0-6/21/2002
057/BR	P10211281-7	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/AU	2002316320	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/AU/DIV	2008243176	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	6/21/2002
057/CA	2455464	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/CN	28185414.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/CN/DIV	2.0081E+11	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/EPO	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/AT	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/FR	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/DE	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/IT	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/ES	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/UK	2746613.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/EPO/DIV	8018517.6	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/EPO/DIV2	EP10182994.3	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/EPO/DIV3	EP10183028	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002

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<b>Docket No.</b>	<b>Serial No.</b>	<b>TITLE</b>	<b>Filed</b>
057/Jp	2003-513435	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/Jp/DIV	2007-207873	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/PCT	PCT/US2002/019676	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
057/BR	P10211281-7	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	06/21/2002
058B/AU	2005208722	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/AU/DIV	2010249161	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/PCT	PCT/US2005/001621	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/CA	2553611	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/CN	2.0058E+11	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/EPO	5711629.5	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/20/2005
058B/Jp	2006-551219	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	07/24/2006
058B/US	10/763,975	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	01/22/2004
059B	10/892,884	ANEURYSM TREATMENT DEVICE AND METHOD OF USE	7/106/2004
504	12/146/252	SELF-EXPANDING PROSTHESIS	06/25/2008
504/PCT	PCT/US2008/068210	SELF-EXPANDING PROSTHESIS	06/25/2008
504/CA	2704920	SELF-EXPANDING PROSTHESIS	06/25/2008
504/CN	200880104160.3	SELF-EXPANDING PROSTHESIS	06/25/2008
504/EP	08771949.8	SELF-EXPANDING PROSTHESIS	06/25/2008
504/Jp	2010-515085	SELF-EXPANDING PROSTHESIS	06/25/2008
521/US	13/003,277	STENT	01/07/2011
521/PCT	PCT/US2010/061627	STENT	12/21/2010



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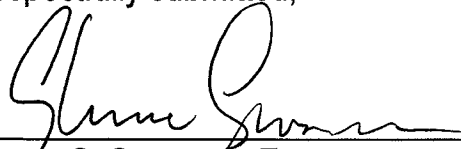
### CONCLUSION

In view of the foregoing, it is submitted that pending claims 23-28, 40, and 41 are now in condition for allowance. Hence, an indication of allowability is hereby requested.

If for any reason direct communication with Applicants' attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any additional fee which may be required in connection with this Amendment to deposit account No. 50-2809.

Respectfully submitted,



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Dated: December 16, 2011

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